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510(k) Summary – K112802

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

Device Name and Classification

Device Trade Name:	Pipeline Total Hip System
Device:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented
Advisory Panel:	Orthopedic

Address and Registration

Submitter's Name:	Pipeline Orthopedics
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810
Date Summary Prepared:	March 2, 2012
Establishment Registration Number	Not yet registered

Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject device is substantially equivalent to the following hip systems or components:

System Components	Predicates
Acetabular Shells – Porous Structured	Biomet Regenerex Ringloc Plus - K070369
Acetabular Shells – Beaded Surface	Consensus Acetabular Shells – K060635

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Acetabular Liners – highly crosslinked Vitamin E polyethylene	StelKast Exp Acetabular Liners – K094035
Acetabular Liners – standard polyethylene	Stryker Trident Acetabular Shell System - K010170
Bone Screws and Dome Hole Occluder	Biomet: Regenerex Ringloc Plus Acetabular Shell System - K070369
Femoral Stems and CoCr Heads	Exactech AcuMatch P-Series Hip Stems – plasma sprayed – K102487, K042842, K041906 Or Smith & Nephew Anthology Plasma Sprayed Hip Stems – K052792

Device Description

The Pipeline Total Hip System is an artificial hip replacement system comprised of femoral stems and mating metal heads; acetabular shells and mating acetabular liners; optional acetabular bone screws; and optional acetabular dome hole occluders.

The Pipeline Femoral Stems are forged titanium alloy, feature a proximal roughened surface (plasma-sprayed CP Titanium), come in a range of sizes, and are offered in two offset neck options per size. The Pipeline Femoral Heads are polished cobalt chromium alloy and come in a range of diameters and extension options.

The Pipeline Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface (titanium alloy). The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The Pipeline Acetabular Liners are manufactured from ultrahigh molecular weight polyethylene (standard UHMWPE or highly crosslinked Vitamin E UHMWPE). The liners are mechanically assembled to the mating shells via engagement of the liner taper with the shell bore. Locking is achieved through engagement of interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell. Poly tabs of the liner mate with scallops on the face of the shell to prohibit rotation of the liner. The liners are available in a range of sizes, and are available in neutral, high wall, +4mm offset, +4mm offset/10° elevated, and +4mm offset/high wall options.

Optional components include a threaded acetabular dome hole occluder and acetabular bone screws, all manufactured from titanium alloy.

Intended Use

Pipeline Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;

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- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Pipeline Total Hip System is intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

Comparison of Technological Characteristics

The metals and standard UHMWPE material from which the components are manufactured are the same materials used in the predicate hip systems and comply with applicable implantable materials standards. The highly crosslinked Vitamin E UHMWPE material complies with applicable implantable materials standards, and the Vitamin E raw material blend in the polyethylene is the same as the predicate highly crosslinked Vitamin E polyethylene. Testing in accordance with the relevant sections of ISO 10993 demonstrates the highly crosslinked Vitamin E polyethylene material's biocompatibility. Further, wear testing demonstrates the suitability of the highly crosslinked Vitamin E UHMWPE for use as an acetabular bearing material in this hip system.

A comparison of design features of the Pipeline Total Hip System to the predicate hip systems, characterization of all porous surfaces in accordance with applicable FDA guidance, and performance testing confirm that the Pipeline Total Hip System is capable of withstanding the anticipated physiological conditions associated with the indications for use and is substantially equivalent to the predicate devices.

Performance Testing

The following performance tests were provided to demonstrate substantial equivalence:

- Biocompatibility testing for the highly crosslinked Vitamin E Polyethylene:
  - Cytotoxicity, 10993-5
  - Maximization/Sensitization, 10993-10
  - Intracutaneous, 10993-10
  - Acute Systemic Toxicity, 10993-11
  - Sub-acute/Subchronic Systemic Toxicity, 10993-11
  - Genotoxicity, 10993-3
  - Muscle Implantation, 10993-6.
- Wear testing: Testing was conducted on 36mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1. Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional gamma sterilized poly under abrasive conditions.
- Wear particle characterization was conducted.
- The highly-crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all

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volatile, semi-volatile, and non-volatile extracts. The results were compared to a predicate material to demonstrate that no new radiation degradation products are released by the material.

- Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 reference material for comparison.
- Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Liner Assembly/Disassembly Testing: Testing of the worst case size Pipeline Hip System highly crosslinked Vitamin E poly acetabular liner and worst case size conventional poly liner were tested for push-out, lever out torque, and axial torque.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.
- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.
- Head/Taper Strength: The average pull off force was demonstrated for the worst-case sizes.
- An analysis was conducted of the typical and worst case ranges of motion permitted by the designs of various liner size/style, head size/style, and stem size/style combinations. The ROM was reported for flexion/extension, abduction/adduction, and internal/external rotation per ISO 21535.
- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws, for the worst-case diameter for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Hip Stem – Plasma-Spray Titanium Coating; and 2) Acetabular Shell – Porous Structured Surface.
- The porous structured surface was evaluated in a transcortical canine model to assess the biological response, using histological and mechanical evaluations, at intervals up to 12 weeks.

Conclusions

The Pipeline Hip System shares the same indications for use as the predicate hip systems, and a comparison of materials and design features, supported by mechanical testing, wear testing, and biocompatibility testing, demonstrates the Substantial Equivalence of the Pipeline Total Hip System to one or more of the predicate hip systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pipeline Orthopedics
% Ms. Terry Powell
M-Squared Regulatory Consultant
901 King Street, Suite 200
Alexandria, Virginia 22314

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Re: K112802
Trade/Device Name: Pipeline Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, OQH, LPH, JDI
Dated: January 30, 2012
Received: February 1, 2012

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112802

Device Name: Pipeline Total Hip System

Indications for Use:

Pipeline Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Pipeline Total Hip System is intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

Prescription Use ___X___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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